Citation:

McCabe LD, Martin BR, McCabe GP, Johnston CC, Weaver CM, Peacock M. Dairy intakes affect bone density in the elderly. *Am J Clin Nutr*. 2004 Oct; 80 (4): 1,066-1,074.

PubMed ID: 15447921

Study Design:

Cross-Sectional Study

Class:

D - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

NEUTRAL: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

- To examine the cross-sectional relationship between consumption of calcium and other nutrients from dairy products and bone mineral density (BMD) at the hip in elderly black and white men and women
- To examine the impact of calcium supplement intake on the BMD loss in a longitudinal study of white men and women.

Inclusion Criteria:

- Men and women
- Black or white in race
- Age 60 years or older.

Exclusion Criteria:

- Terminal illness
- Paget's disease of the bone
- Recurrent urinary stone disease
- Treatment with sodium fluoride, biphosphonate, or dilantin
- Renal disease requiring specific treatment
- Disapproval by the primary physician of the subject.

Description of Study Protocol:

Recruitment

Elderly men and women were recruited from the Indianapolis area to participate in either a cross-sectional study (black and white participants) or cross-sectional and longitudinal study (white participants only) of dairy and bone density.

Design

- Cross-sectional study of dairy and BMD in black and white, men and women over the age of 60 years
- Longitudinal study of the effect daily calcium or vitamin D supplementation on preventing BMD loss in white men and women over the age of 60 years old.

Dietary Intake/Dietary Assessment Methodology

HHHQ-DIETSYS (National Cancer Institute) was used to collect dietary intake information. The questionnaire was modified to include yogurt and frozen yogurt to more completely capture dairy food intake.

Blinding Used

For longitudinal study, double-blinding for intervention was used.

Intervention

White subjects participated in a four-year, placebo-controlled study wherein participants received daily placebo, 750mg Ca per day, or 15mcg per day 25-hydroxyvitamin D3 per day.

Statistical Analysis

- Two-way ANOVA was used to examine differences in antropometric, micronutrient intake, dairy product intake associated with sex and race. Tukey's multiple comparison procedure was used to determine statistical differences between the four sex-by-race groups
- For the cross sectional data, partial correlations between BMD and nutrients from dairy and non-dairy sources, after removing the linear effects of race, weight and age, were examined. A partial regression plot was used to visually describe the adjusted relation between total hip BMD and dairy calcium intake in men and women
- For the longitudinal data, a repeated ANOVA was used to assess dietary information. Multiple regression models were used to evaluate the percentage change in total hip and femoral neck BMD in subjects that consumed less than or greater than 1.5 servings of dairy per day and in those who were older or younger than the median age of 72 years old
- SAS software was used for all statistical analysis.

Data Collection Summary:

Timing of Measurements

- Dietary information: Baseline (all participants), every six months for four years (longitudinal study participants only)
- BMD: Baseline (all participants), every six months for four years (longitudinal study participants only).

Dependent Variables

BMD: Bone mineral density of total hip and femoral neck [measured using dual-energy X-ray absorptiometry (DEXA)]

Independent Variables

- Race
- Sex
- Dietary intake (dairy and non-dairy nutrients)
- Dietary supplement group (longitudinal study).

Control Variables

- Weight
- Age.

Description of Actual Data Sample:

- *Initial N:* 745
  - White women N=289
  - White men N=116
  - Black women N=265
  - Black men N=75
- *Attrition (final N):* Complete diet and BMD available for 181 longitudinal participants
  - Calcium supplement group N=60
  - Vitamin D supplement group N=61
  - Placebo supplement group N=60
- *Age:* Over 60 years (median age 72 years)
- *Ethnicity:* Black and white
- *Other relevant demographics:* None
- *Anthropometrics:*
  - White men were the oldest of the four cross-sectional groups
  - White women had the lowest average weight of the four groups
  - Black women weighed less than the black men but not less than the white men
  - For total hip and femoral neck BMD, the black participants had higher values than the white participants, and the men had higher average values than the women
- *Location:*
  - White participants were recruited from Franklin, IN (a suburban area, 15 miles from Indianapolis)
  - Black participants were recruited from Indianapolis, IN (urban area).

Summary of Results:

Cross-sectional Study

- For all participants, average total calcium intake from dairy was 436±289mg and 239±93mg from non-dairy dietary sources
- Overall, men had significantly higher consumption of most macro- and micronutrients examined by the authors
- There was no statistical difference in the amount of calcium consumed from dairy sources among the four groups
- The relationship between diet and bone measures did not depend on race
- The relationship between diet and bone measures depended on gender (P for interaction =0.0092 for total hip BMD and P for interaction for femoral neck BMD=0.04)
- A partial positive correlation was found between total hip BMD and dairy calcium in men

(P<0.05, r=0.23), but not in women (P>0.05, r=0.02)

- In men only, positive partial correlations (P<0.05) were found between both total hip and femoral neck BMD and the following nutrients from dairy:
  - Total energy (r= 0.18)
  - Carbohydrate (g) (r= 0.15)
  - Protein (g) (r= 0.23)
  - Vitamin A (r= 0.20)
  - Retinol (g) (r= 0.20)
  - Folate (g) (r= 0.23)
  - Thiamine (mg) (r= 0.21)
  - Riboflavin (mg) (r= 0.22)
  - Niacin (mg) (r= 0.23)
  - Pyridoxine (mg) (r= 0.22)
  - Vitamin C (mg) (r= 0.21)
  - Magnesium (mg) (r= 0.21)
  - Potassium (mg) (r= 0.21)
  - Sodium (mg) (r= 0.18)
  - Zinc (mg) (r= 0.20)
- Regression analysis found that the age, weight, and race explained 29% of total hip and 33% of femoral hip BMD in men (P<0.0001), and 44% of total hip and 42% of femoral hip BMD in women (P<0.0001). Higher BMD were generally associated with heavier, younger, black and male participants.

Total Dietary Nutrient Intake						
	Men		Women			
Nutrient	Black (N=75	White (N=116)	Black (N=265)	White (N=289)	P-value for Race	P-value for Sex
Total energy (kcal)	1,776±571	1,588±436	1,300±429	1,200±352	<0.05	<0.05
Calcium (mg)	801±400	693±279	672±335	639±288	<0.05	<0.05
Calcium:Phosphorus ratio	0.66±0.14	0.63±0.11	0.72±0.14	0.70±0.13	<0.05	<0.05

Total Dairy Nutrient Intake						
	Men		Women			
Nutrient	Black (N=75)	White (N=116)	Black (N=265)	White (N=289)	P-value for Race	P-value for Sex
Total energy (kcal)	254±189	249±148	220±148	217±131		<0.05

Longitudinal Study

- The effect of calcium supplementation on femoral neck BMD depended on baseline dietary calcium intake ($P<0.05$ for interaction). Those participants with deficient diets (<1.5 servings or <450 mg Calcium per day) at baseline who were treated with calcium had less change in femoral neck BMD compared to those treated with placebo
- The effect of calcium supplementation was evident in those that were less than 72 years old at baseline but not in those that were older than 72 years at baseline.

Author Conclusion:

- Cross-sectional results indicated that higher dairy product consumption is associated with greater hip BMD in men, but not in women
- Calcium supplementation protected both men and women from bone loss in the longitudinal study of whites.

Reviewer Comments:

- *Article was noted as D class because the majority of the results pertained to the cross-sectional arm of the study*
- *The overall conclusions stated by the authors did not specify the interactions between baseline intake and age that were noted in the results*
- *The authors did not appear to apply a post-hoc test to differentiate between groups for the interactions reported in the longitudinal results. Although a P-value was reported for the interaction, differences would hold more weight if a significance test was associated with the group differences that the authors discuss*
- *The authors do not describe the source of participant attrition for the longitudinal study*
- *The white participants who received vitamin D treatment are included in the participant description for the longitudinal study, but are not discussed in the findings*
- *It is not clear if the longitudinal results would extend to a non-white population*
- *The effects on results of recruiting subjects from different settings for the two races (rural vs. urban) is not discussed by the authors.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes

4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions

1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	???
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	N/A
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	No
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	Yes
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	???
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A
4.	**Was method of handling withdrawals described?**	No

4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	No
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	No
4.4.	Were reasons for withdrawals similar across groups?	???
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	???
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	???
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	???
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	N/A
6.6.	Were extra or unplanned treatments described?	N/A
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	N/A
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A

7.	**Were outcomes clearly defined and the measurements valid and reliable?**		Yes
	7.1.	Were primary and secondary endpoints described and relevant to the question?	N/A
	7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
	7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
	7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
	7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
	7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
	7.7.	Were the measurements conducted consistently across groups?	Yes
8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		No
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	No
	8.2.	Were correct statistical tests used and assumptions of test not violated?	???
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	N/A
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	N/A
	8.6.	Was clinical significance as well as statistical significance reported?	???
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	No
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		No
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	No
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes